



## Information Sheet

### System Validation in the Pharmaceutical Industry

Validation is an integral part of current good manufacturing practice. It is therefore also an element of Quality Assurance. Validation should be considered as part of the complete life cycle of a computer system. This cycle includes the stages of planning, specification, programming, testing, commissioning, documentation, operation, monitoring and modifying.

Computer system validation is the process of documenting that a specific computer system meets the critical user requirements, and that provisions are made to ensure continuous fulfilment of this requirement throughout its complete life cycle.

The extent of validation will depend on a number of factors:

- The use to which the system is to be put
- Whether the validation is to be prospective or retrospective
- Whether novel elements are incorporated

A Validation Master Plan (VMP) shall specify a set of strategies chosen to qualify the system's major components. The document shall also specify any other actions, approvals and documents necessary to obtain the validation status.

A validation protocol should clearly describe the procedure to be followed for performing the validation. A validation report should be available after completion of the validation.

The validation of equipment, facilities and services is referred to as qualification.

An Installation Qualification (IQ) protocol is used to document the specific attributes of a system in order to prove that the installation has been correctly performed and that the installation specifications of the manufacturer have been met. The IQ data should be reviewed and approved before operational qualification (OQ) commences.

The purpose of OQ is to document that all critical functional requirements have been challenged and met throughout all operational ranges. The OQ data shall be formally reviewed and approved before performance qualification (PQ) can commence, unless data is being gathered over a long period.

PQ tests shall verify that the systems as connected together in the target environment can perform effectively and reproducibly. PQ tests shall involve trained operators and specific standard operating procedures supported by system design experts.

For cross-site information systems, the system shall be validated at a central site by the system owner. Thereafter each site management shall be responsible for local verification of the relevant, specific IQ-related activities.



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Changes occurring during the qualification shall be approved by the person responsible for supplier quality.

The validation status shall be evaluated annually in order to maintain the system in a validated state. If the evaluation concludes that the system needs to be reassessed, a plan for revalidation shall be established.

### References:

1. Pharmaceutical Inspection Convention Guide to Good Manufacturing Practice
2. Medicines Control Council Guide to Good Manufacturing Practice



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